



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0101]

Duniel Tejeda: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debaring Duniel Tejeda from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Duniel Tejeda was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product under the FD&C Act. Duniel Tejeda was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of April 20, 2022 (30 days after receipt of the notice), Mr. Tejeda had not responded. Mr. Tejeda's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On January 20, 2022, Mr. Duniel Tejeda was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Southern District of Florida-Miami Division, when the court accepted his plea of guilty and entered judgment against him for one count of conspiracy to commit mail and wire fraud in violation of 18 U.S.C. 1349.

As contained in the indictment, entered into the docket on February 24, 2021, and the Factual Proffer in support of Mr. Tejeda's guilty plea, entered into the docket on October 26, 2021, both from his case, Mr. Tejeda was a project manager and study coordinator employed at Tellus Clinical Research, Inc. ("Tellus"). Tellus was a medical research clinic located in Miami, Florida that conducted clinical trials on behalf of pharmaceutical companies and other sponsors. Among the clinical research trials conducted by Tellus were two studies of an investigational drug intended to treat opioid dependency, sponsored by Sponsor 1 and managed by clinical research organization (CRO) 1 (collectively, "the opioid dependency trials"); two studies of an investigational drug intended to treat irritable bowel syndrome in female subjects, sponsored by Sponsor 2 and managed by CRO 2 (collectively, "the IBS trials"); and one study of an investigational injectable drug intended to treat diabetic nephropathy, sponsored by Sponsor 3 and managed by CRO 3 ("the diabetes trial"). In Mr. Tejeda's roles with Tellus, he conspired with others to defraud these sponsors and CROs responsible for initiating and overseeing these clinical trials. For the purpose of obtaining money by means of materially false and fraudulent

pretenses, representations, and promises, Mr. Tejeda, along with his co-conspirators, caused false information to be entered in subject case histories to make it appear that subjects had, among other things, satisfied the eligibility criteria to participate in the studies, provided informed consent to participate in the studies, received proper physical examinations, received or had been administered the investigational drug that was the subject of each clinical trial, and received payments for visits to Tellus for the clinical trials, when in fact Mr. Tejeda knew that such events had not occurred. As an example of Mr. Tejeda's specific conduct to further this scheme, in one of the opioid dependency trials, Mr. Tejeda entered his initials in the case history documentation for one of the study subjects to represent falsely that he had administered multiple doses of the investigational drug to the subject as required by the study protocol, and that this drug administration was witnessed by one of Mr. Tejeda's co-conspirators. As Mr. Tejeda well knew, these representations were false because the study subject was not participating in the study, Mr. Tejeda did not dose them with the study medication, and the dosing was not witnessed by Mr. Tejeda's co-conspirator.

In another instance, in connection to one of the IBS trials, Mr. Tejeda wrote a check, endorsed by one of his co-conspirators, to a study participant for their purported participation in a study visit. As Mr. Tejeda well knew, the individual was not in fact participating in the study and had not received the check. Mr. Tejeda deposited that check in his own bank account. Further, as part of the IBS trials, study subjects were required to make daily phone calls to an "e-diary" system (a toll-free number maintained by a third party) and report their personal experience with the study drug. Using the subjects' individual personal identification numbers, Mr. Tejeda, along with one or more of his co-conspirators, placed telephone calls to this e-diary system for the purposes of reporting fabricated data on behalf of purportedly legitimate study subjects.

As a result of this conviction, FDA sent Mr. Tejeda by certified mail on March 1, 2022, a notice proposing to permanently debar him from providing services in any capacity to a person

that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Mr. Tejeda was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Mr. Tejeda an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning his debarment. Mr. Tejeda received the proposal on March 21, 2022. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Tejeda has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Tejeda is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act. Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Tejeda in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If during his period of debarment Mr. Tejeda provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or

review any abbreviated new drug application from Mr. Tejeda during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a “drug product” is defined as a “drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]” (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Tejeda for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2022-N-0101 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: July 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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